IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

BENJAMIN P. SALVIO, Individually and as Administrator of the Estate of JANINE M. TRAGESSER, Deceased,	)	
Plaintiff,	)	Civil Action No. 2:11-cv-00553-TFM
v.	)	
	)	ELECTRONICALLY FILED
AMGEN, INC., a Delaware corporation; IMMUNEX, INC., a wholly owned subsidiary of AMGEN, INC.; WYETH, LLC, a Delaware corporation; and PFIZER, INC., a Delaware corporation,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S 1st AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM PURSUANT TO FED. R. CIV. P. 12(b)(6)

Defendants Amgen Inc. (improperly referred to as Amgen, Inc. in the 1st Amended Complaint), Immunex, Inc., Wyeth, LLC, and Pfizer Inc (hereinafter, "Defendants") hereby submit their Memorandum of Law in Support of their Motion to Dismiss Plaintiff's 1st Amended Complaint for Failure to State a Claim. Benjamin P. Salvio, individually and as Administrator of the Estate of Janine M. Tragesser, (hereinafter, "Plaintiff"), has filed this product liability action against Defendants, alleging that Janine M. Tragesser (hereinafter, "Decedent") was injured as a result of her use of Enbrel®, a biological product approved by the United States Food and Drug Administration ("FDA") for the treatment of rheumatoid arthritis and other serious conditions. Enbrel® has been on the market since 1998. It is available only by prescription and is supplied

with a Package Insert, clearly and comprehensively warning the prescribing physician of the potential risks associated with Enbrel®, including the injury alleged here: infection.

The 1st Amended Complaint attempts to hold Defendants liable under three different theories of liability: negligence (First Claim), strict liability (Second and Third Claim), and breach of warranty (Fourth and Fifth Claims). These five underlying claims are brought both as a survival action (Seventh Claim) and as a wrongful death action (Eight Claim), pursuant to 42 Pa. Cons. Stat. § 8302 and 42 Pa. Cons. Stat. § 8301, respectively. Plaintiff also makes a claim for gross negligence/punitive damages (Sixth Claim). Although not entirely clear, the three theories of recovery – namely, negligence, strict liability, and breach of warranty – purport to be based on vague, unspecified design and manufacturing defects, along with a failure to warn of Enbrel®'s dangerous propensities.[1] Yet Pennsylvania does not recognize claims for strict liability and breach of warranty in the prescription drug context. And the remaining claim for negligence does not satisfy the heightened "plausibility standard" recently articulated by the Supreme Court in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), especially in light of the learned intermediary doctrine and the Package Insert accompanying Enbrel®. Indeed, the Package Insert warned Decedent's prescribing physician of the risk of serious and fatal infections, the precise injury alleged here. Further, Plaintiff's claim for punitive damages should be dismissed because Plaintiff has not adequately pleaded the requisite intent necessary to sustain such a claim. As such, Plaintiff's 1st Amended Complaint should be dismissed in its entirety.

[1] While Plaintiff appears to allege design, manufacturing, and failure to warn defects under the negligence claim, (*see* Cmplt., Lines 289-332), Plaintiff only brings strict liability claims for design and failure to warn defects. (*See id.*, Lines 350-390).

FACTUAL BACKGROUND

Rheumatoid arthritis is a debilitating condition in which the immune system attacks joints, cells, tissues around the joints, and potentially other organs of the body. In 1998, Enbrel® was approved for the treatment of rheumatoid arthritis and is credited with revolutionizing treatment options for sufferers of this disease. *See* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm080536.htm.[2] Since its initial approval, the FDA has approved the expanded uses of Enbrel® for various other indications. http://www.enbrel.com/what-is-ENBREL.jspx.[3]

Decedent began taking Enbrel® to treat her rheumatoid arthritis sometime in 2001. (*See* Cmplt., Lines 120-121).[4] Approximately seven years later, sometime in 2008, Decedent allegedly developed mucormycosis, (*id.* at Lines 121-125, 239-240), which is a fungal infection of the sinuses, brain, or lungs that occurs mostly in people with weakened immune systems. *See* http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001672/. The infection allegedly caused Decedent to experience significant respiratory problem, and on May 13, 2010, approximately

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[2] Enbrel® is considered a biologic response modifier or biologic. *See* http://www.enbrel.com/what-is-ENBREL.jspx. By working on the immune system, biologics such as Enbrel® block proteins that contribute to the disease process. *See id.*; *see also* "FDA 101: Regulating Biological Products," available at http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm048367.pdf. People with certain inflammatory diseases, including rheumatoid arthritis, have too much TNF in their bodies, and Enbrel® can reduce that amount. *See* http://www.enbrel.com/what-is-ENBREL.jspx.

[3] Enbrel® has more than seventeen (17) years of collective clinical experience. *See* http://www.enbrel.com/what-is-ENBREL.jspx. Since its initial approval for rheumatoid arthritis in 1998, Enbrel® has been approved by the FDA to treat moderate to severe plaque psoriasis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis, and ankylosing spondylitis. *See id.*

[4] Because the time period of Decedent's alleged use of Enbrel® pre-dates the date upon which Pfizer Inc acquired Wyeth (October 15, 2009), Pfizer Inc is not a proper party to this lawsuit.

two years after she developed the infection, she passed away. (*Id.* at Lines 126-129, 146-147). Plaintiff alleges that Enbrel® caused Decedent to develop mucormycosis and her subsequent injuries. Plaintiff further alleges that given Decedent's co-morbidity factors such as diabetes, she would not have taken Enbrel® had she known about the risk of death. (*Id.* at Lines 137-139).

But Plaintiff's prescribing physician was specifically warned of the risk of potentially fatal infections because the Package Insert in effect when Decedent was prescribed Enbrel® warns clearly and expressly of this potential risk and other possible adverse events. *See* Enbrel® Package Insert, pp. 11-20 (January 2001 #0311-07) (attached as Exhibit A).[5] The warning regarding the risk of serious and fatal infections is printed in bold font and capitalized and is the first warning listed on the Package Insert:

> **WARNINGS**
>
> **INFECTIONS**
>
> **IN POST-MARKETING REPORTS, SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF ENBREL®. MANY OF THE SERIOUS INFECTIONS HAVE OCCURRED IN PATIENTS ON CONCOMITANT IMMUNOSUPPRESSIVE THERAPY THAT, IN ADDITION TO THEIR UNDERLYING DISEASE, COULD PREDISPOSE THEM TO INFECTIONS. RARE CASES OF TUBERCULOSIS (TB) HAVE BEEN OBSERVED IN PATIENTS TREATED WITH TNF ANTAGONISTS, INCLUDING ENBREL®. PATIENTS WHO DEVELOP A NEW INFECTION WHILE UNDERGOING TREATMENT WITH ENBREL® SHOULD BE MONITORED CLOSELY. ADMINISTRATION OF ENBREL® SHOULD BE DISCONTINUED IF A PATIENT DEVELOPS A SERIOUS INFECTION OR SEPSIS. TREATMENT WITH ENBREL® SHOULD NOT BE INITIATED IN PATIENTS WITH ACTIVE INFECTIONS, INCLUDING CHRONIC OR LOCALIZED INFECTIONS. PHYSICIANS SHOULD EXERCISE CAUTION WHEN CONSIDERING**

[5] It is unclear from the 1st Amended Complaint precisely when in 2001 Decedent began using Enbrel®. Yet the warning language for infections contained in other Package Inserts issued in 2001 is identical to the warning language cited above. *See* Enbrel® Package Insert, p. 11 (January 2001 #0311-08 and July 2001 #10662-09) (attached collectively as Exhibit B).

THE USE OF ENBREL® IN PATIENTS WITH A HISTORY OF RECURRING INFECTIONS OR WITH UNDERLYING CONDITIONS WHICH MAY PREDISPOSE PATIENTS TO INFECTIONS, SUCH AS ADVANCED OR POORLY CONTROLLED DIABETES (see PRECAUTIONS and ADVERSE REACTIONS: Infections).

Id. at p. 11. Further, warnings of infections are repeated under the **"ADVERSE REACTIONS"** section. *See id.* at p. 15.[6]

Despite these clear warnings of the very injury alleged in this case, infection, Plaintiff asserts five causes of action against Defendants.[7] Not only are several of these claims not cognizable under Pennsylvania law, Plaintiff merely recites the legal elements of each claim without much, if any, factual support. Accordingly, these claims should be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

LEGAL STANDARD

I. THE PLAUSIBLE CLAIM STANDARD FOR PLEADINGS

The stringent test used to evaluate a complaint under Rule 12(b)(6) is clear. In its landmark 2007 decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), the Supreme Court heightened the pleading standard applicable to evaluating a motion to dismiss under Rule 12(b)(6). The Court found that a complaint must contain "enough facts to state a claim for relief

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[6] Plaintiff's allegations that Defendants failed to accompany Enbrel® with adequate warnings, (*see* Cmplt., Lines 134-137, 175-186, 203-206, 301-303, 329-330, 367-390), effectively incorporate the package insert as an integral part of Plaintiff's claims, and thus may be considered by the Court when assessing this motion to dismiss. *See Moore v. Watson Pharma.*, No. CIV.A. 01-4260, 2002 WL 63592, at * 2 (E.D. Pa. 2002) (stating that the court could consider the Physician's Desk Reference (PDR) in evaluating the defendant's motion to dismiss because the plaintiff's claims were based on the warnings listed in the PDR).

[7] As noted above, Plaintiff asserts the following: negligence (First Claim), strict liability: design defect (Second Claim), strict liability: failure to warn (Third Claim), breach of express warranty (Fourth Claim), and breach of implied warranty (Fifth Claim). Plaintiff also asserts claims for gross/negligence punitive damages (Sixth Claim), survival action (Seventh Claim), and wrongful death action (Eight Claim), all based on the five underlying causes of action.

that is plausible on its face." *Id.* at 570. This requires plaintiffs to "nudge[ ] their claims across the line from conceivable to plausible." *Id.* Also, in order to avoid the unnecessary burden and expense associated with allowing implausible cases to proceed to discovery, bald assertions and unsupportable conclusions or inferences will not suffice. *Id.* at 556-57. Under *Twombly*, "the mere metaphysical possibility that *some* plaintiff could prove *some* set of facts in support of the pleaded claims is insufficient; the complaint must give the court reason to believe that *this* plaintiff has a reasonable likelihood of mustering factual support for *these* claims." *Ridge at Red Hawk, L.L.C. v. Schneider*, 493 F.3d 1174, 1177 (10th Cir. 2007) (emphasis in original).

The Supreme Court further elaborated on the "plausibility standard" in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), where the Court set forth a two-step process for courts to follow when analyzing a motion to dismiss. First, although "a court must accept as true all of the allegations contained in a complaint," that tenet is inapplicable to legal conclusions, and "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949. Second, with respect to any surviving well-pleaded factual allegations, "a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 1950. In defining plausibility, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do." *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 555). Also, "'naked assertions' devoid of 'further factual enhancement'" are insufficient. *Id.* (quoting *Twombly*, 550 U.S. at 557). Since *Iqbal,* this Court has applied its criteria in a number of recent decisions, resulting in the dismissal of insufficiently pleaded claims. *See, e.g.*, *Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *8-11 (W.D. Pa. June 16, 2010) (dismissing insufficiently pleaded negligence, strict liability, and breach of warranty claims asserted against manufacturers of a medical device and

manufacturers of a prescription drug that was administered through the device). Plaintiff falls short of meeting these standards.

ARGUMENT

I. PLAINTIFF'S ALLEGATIONS FAIL TO STATE COGNIZABLE CLAIMS AND/OR FAIL TO SATISFY THE APPLICABLE PLEADING STANDARD UNDER PENNSYLVANIA LAW

Plaintiff's 1st Amended Complaint should be dismissed in its entirety because the strict liability and breach of warranty claims are not cognizable under Pennsylvania law against the manufacturer of prescription drugs, and the remainder of the 1st Amended Complaint is precisely the type of bare bones pleadings that is legally insufficient under *Twombly* and *Iqbal*. Indeed, the remaining negligence claim against Defendants consists almost entirely of a formulaic recitation of the legal elements of the claim. Further, even if the negligence claim contains well-pleaded factual allegations, it *cannot* satisfy the plausibility standard even if pleaded with particularity because of the learned intermediary doctrine. The 1st Amended Complaint thus should be dismissed in its entirety.

a. Plaintiff's Strict Liability and Breach of Warranty Claims Are Not Cognizable under Pennsylvania Law

Since Pennsylvania's adoption of comment k to the Restatement (Second) of Torts § 402A, strict liability and breach of warranty claims cannot be sustained against the manufacturer of prescription drugs. Thus, Plaintiff's strict liability and breach of warranty claims contained in the Second, Third, Fourth, and Fifth Claims should be dismissed. Each is addressed in turn.

1. Strict Liability: Design Defect

Under Pennsylvania law, a design defect claim for strict liability is not cognizable when it is asserted against a manufacturer of prescription drugs. *Lance v. Wyeth*, 4 A.3d 160, 165 (Pa.

Super. Ct. 2010) (concluding that Plaintiff's first cause of action duplicated a strict liability design defect claim and was properly disposed of by the trial court); *see also Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984) ("[A]ssuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk."). This conclusion results from Pennsylvania's adoption of comment k to § 402A, *see Lance*, 4 A.3d at 165, which governs "unavoidably unsafe products," and provides that "[s]uch a product [e.g. a prescription drug], properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." Restatement (Second) of Torts § 402A comment k. While comment k includes two caveats, namely that the drug must be properly prepared and accompanied with proper warnings, these caveats are evaluated under negligence principles, which are discussed below. *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (citing *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996)). Because the strict liability design defect claim is not sustainable under Pennsylvania law, the Second Claim should be dismissed with prejudice.

2. Strict Liability: Failure to Warn

Similarly, under Pennsylvania law, a failure to warn claim for strict liability is not cognizable when it is asserted against a manufacturer of prescription drugs. *Hahn*, 673 A.2d at 891. As the Supreme Court of Pennsylvania explained in *Hahn*, "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Id.* Since *Hahn*, courts applying Pennsylvania law "have consistently held that negligence is the only theory upon which a prescription drug manufacturer can be held liable

for a failure to warn." *Kline v. Pfizer, Inc.*, C.A. No. 08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008); *see also Kester*, 2010 WL 2696467, at *9 (dismissing a strict liability claim based on failure to warn). This Court should do the same here and dismiss the Third Claim with prejudice.

3. Breach of Express Warranty

To the extent that Plaintiff's claim for breach of warranty is based on Enbrel®'s allegedly inadequate warnings, it, like the claims discussed above, should be dismissed because under Pennsylvania law, only claims sounding in negligence can be asserted against pharmaceutical manufacturers such as the Defendants in this case. *See Hahn*, 673 A.2d at 891; *see also Kline*, 2008 WL 4787577, at *4 (dismissing claims for breach of express warranty and breach of implied warranty based on the language of *Hahn*); *Aaron v. Wyeth*, No. 2:07cv927, 2010 WL 653984, at *11 (W.D. Pa. Feb. 19, 2010) (same).

But there is more. The 1st Amended Complaint also lacks factual allegations sufficient to state a claim for breach of express warranty. Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. Cons. Stat. § 2313(a)(1); *see also Parkinson*, 315 F. Supp. 2d at 751 ("[A]n express warranty arises out of the representations or promises of the seller."). Additionally, "[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." 13 Pa. Cons. Stat. § 2313(a)(2). Notably, Plaintiff does not allege any affirmation, fact, promise, or description that became part of the basis of the bargain when Decedent first purchased Enbrel®. While Plaintiff vaguely alleges that there were "statements and representations [made] concerning the product at issue,"

(Cmplt., Lines 413-414), and that Defendants "expressly warranted to [Decedent] and her doctors that the product was merchantable and fit for the purpose intended," (*id.*, Lines 421-423), no facts are given to support such allegations.[8] Such a bare pleading does not meet the stringent tests of *Iqbal* and *Twombly*, and the claim should be dismissed. *See Parkinson*, 315 F. Supp. 2d at 752 (dismissing an insufficiently pleaded claim for breach of express warranty); *Kester*, 2010 WL 2696467, at *11 (same).

4. Breach of Implied Warranty

Similarly, to the extent that Plaintiff's 1st Amended Complaint is based on Enbrel®'s allegedly inadequate warnings, Pennsylvania law requires that the breach of implied warranty claim also be dismissed. *See Hahn*, 673 A.2d at 891; *see also Kline*, 2008 WL 4787577, at *4 (dismissing claims for breach of express warranty and breach of implied warranty based on the language of *Hahn*); *Aaron*, 2010 WL 653984, at *11 (same). Further, Pennsylvania courts have explicitly stated "that the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes' . . . ." *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 377 (Pa. 1987); *see also Murray v. Synthes U.S.A., Inc.*, No. Civ.A. 95-7796, 1999 WL 672937, at *9 (E.D. Pa. Aug. 23, 1999) (extending this reasoning to prescription medical devices to dismiss a claim against a manufacturer of bone screws for breach of implied warranty of merchantability). Based upon this precedent, Plaintiff cannot state a claim for breach of implied warranty under Pennsylvania law, and this claim should be

[8] Plaintiff similarly states that "[e]ach Defendant made claims regarding the health benefits of ingesting Enbrel®," (*id.*, Line 201), and that "Defendants . . . advertised Enbrel® as safe and effective . . . ." (*Id.*, Lines 217-218). But again, Plaintiff does not identify the precise statements that were made that would have created such an express warranty.

dismissed with prejudice. *See Kester*, 2010 WL 2696467, at *11 (dismissing an insufficiently pleaded claim for breach of implied warranty).

b. Plaintiff's Negligence Claim Fails Because Plaintiff Has Not Alleged Facts to Support Each Element of the Claim

As the above discussion demonstrates, Pennsylvania law concerning prescription drugs is clear: In order to state a product liability claim against a prescription drug manufacturer, the claim must sound in negligence. While Plaintiff alleges a laundry list of allegedly negligent actions in the First Claim of the 1st Amended Complaint, they can be grouped generally into five types: negligent design, negligent manufacture, negligent failure to warn, negligent failure to test/inspect, and negligent marketing/promotion. (*See* Cmplt., Lines 289-332). Each category of negligent claims fails for the reasons discussed below.

As an initial matter, Pennsylvania does not recognize a separate tort for negligent failure to test or negligent marketing. *See Wolfe v. McNeil-PPC, Inc.*, C.A. No. 07-348, 2011 WL 1157927, at *6 (E.D. Pa. March 30, 2011) (stating that a tort for negligent failure to test is subsumed within a defective design or defective manufacture claim, and that a tort for negligent marketing can only be brought if the manner in which a drug is promoted negates *otherwise-adequate* warnings); *see also Lance*, 4 A.3d at 169 (stating that a tort for negligent failure to test is subsumed within a defective design or failure to warn claim). To the extent Plaintiff's negligence claim is based upon such allegations, (*see* Cmplt., Lines 295-299, 311-312, 317-324), it must be dismissed. As such, Plaintiff's negligence claim can be based only on a negligent design, negligent manufacture, or negligent failure to warn theory. But these claims should be dismissed as well.

Broadly speaking, to state a claim for negligence in a products liability suit, "the plaintiff must prove that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries." *Parkinson*, 315 F. Supp. 2d at 749. This Plaintiff does not do. Rather, Plaintiff merely recites the legal elements, which is insufficient under *Iqbal* and *Twombly*, warranting the dismissal of Plaintiff's negligence claim.

1. Negligent Design/Manufacture

To the extent Plaintiff's claim for negligence is based on a negligent design or negligent manufacture of Enbrel®, this claim must fail because Plaintiff has not alleged sufficient facts to meet the standard for negligence set forth above. Under the First Claim, Plaintiff merely alleges that Defendants failed to use due care in the design and manufacture/development of Enbrel® to prevent risks to consumers who ingested the drug, (*see* Cmplt., Lines 289-290, 292-293, 305-309), and that this failure was the direct and proximate cause of Decedent's injuries. (*See* Cmplt., Lines 343-344). Simply listing these elements is insufficient. Plaintiff provides no facts from which this court can ascertain how Defendants breached their duty of care and how Defendants were negligent in their design or manufacture of Enbrel®. *See Aaron*, 2010 WL 653984, at *11 ("[T]he determination of whether a product was negligently designed turns on whether an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered.") (internal quotations and citation omitted).[9] Plaintiff has simply not satisfied the

[9] Importantly, Pennsylvania has only recently articulated that a claim for negligent design can be brought notwithstanding comment k to § 402A, which precludes claims for strict liability based on design defects. *See Lance*, 4 A.3d at 165-166. In light of this determination by the Superior Court of Pennsylvania, on March 11, 2011, the Supreme Court granted a Petition for Allowance of Appeal to determine whether a plaintiff can in fact bring a negligent design claim against a prescription drug manufacturer under Pennsylvania law. *Lance v. Wyeth*, 15 A.3d 429, 430 (Pa.

applicable pleading standard, and any claim of negligence based on a design or manufacturing defect must therefore be dismissed.

2. Failure to Warn

To the extent Plaintiff's claim for negligence is based on a negligent failure to warn, Plaintiff's claim also fails as a matter of law. As the Supreme Court of Pennsylvania instructed in *Hahn*, the standard of care applicable to evaluating a negligent failure to warn claim is set forth in the Restatement (Second) of Torts § 388 and provides that "a manufacturer is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Parkinson*, 315 F. Supp. 2d at 748 (quoting *Baldino*, 478 A.2d at 810); *see also Hahn*, 673 A.2d at 890; Restatement (Second) of Torts § 388. Therefore, to properly allege failure to warn, Plaintiff must articulate how Enbrel®'s accompanying warnings were inadequate because Pennsylvania will not hold a drug manufacturer liable if reasonable care was taken to provide users of Enbrel® with adequate warnings. *See Parkinson*, 315 F. Supp. 2d at 748 (stating that since the warning issued "was not inadequate," the defendants met the standard of care required by § 388); *Aaron*, 2010 WL 653984, at *11 (dismissing the plaintiff's failure to warn claim since the plaintiff was unable to show that the defendant's warnings were inadequate).

Such facts are blatantly missing from the 1st Amended Complaint. Plaintiff repeats only general allegations that Defendants "failed to warn of the true risks and dangers, and of the symptoms, scope and severity of the potential side effect of the drug Plaintiff ingested . . . [which] include, but are not limited to serious infections requiring hospitalizations, and death." (Cmplt.,

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2011). In the meantime, assuming Plaintiff can bring such a claim, the allegations do not sufficiently state a claim for relief as Plaintiff makes no attempt to specify these allegedly "safer alternatives" that were available. (*See* Cmplt., Lines 336-337).

Lines 373-376).[10] Again, such allegations do not specify how Defendants breached their duty of care, especially in light of the Package Insert, which clearly and explicitly warns of the risk of serious infections and death. *See* Enbrel® Package Insert, pp. 11-20 (January 2001 #0311-07) (stating that "SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF ENBREL®."). For these reasons, any claim of negligence based on a failure to warn should therefore be dismissed.

Even if, however, Plaintiff has somehow alleged facts sufficient to overcome the first prong of *Iqbal*, which Defendants do not concede, the facts do not plausibly give rise to an entitlement to relief based on the learned intermediary doctrine. Moreover, Plaintiff has not adequately alleged causation.

c. Plaintiff's Negligence Claim Fails Because Decedent's Physician Was Adequately Warned of the Side Effects of Enbrel®

Under Pennsylvania law, "a prescription drug manufacturer may meet its duty to warn by providing an adequate warning to a learned intermediary as opposed to the general public or individual users. *See Parkinson*, 315 F. Supp. 2d at 748-49 (internal quotations and citation omitted). This learned intermediary doctrine provides that in order for Plaintiff to recover on a theory of failure to warn, sufficient facts must be alleged to show that the *physician* was inadequately warned. Plaintiff simply cannot meet this burden. While Plaintiff alleges that "there is no evidence that the defendants informed [Decedent's] prescribing doctor about the risk of death," (Cmplt., Lines 135-137), and that "Defendants did not inform doctors prescribing Enbrel® to their patients that the drug can kill you," (*id.*, Lines 179-180), as noted above, the

[10] Plaintiff further alleges that Decedent "never was told about the risk of death," (Cmplt., Lines 134-137), that Defendants "understated the risk of such serious infections leading to death," (*id.*, Lines 175-178), and that Defendants "failed to adequately disclose . . . the risk of fatal fungal infections." (*Id.*, Lines 203-206).

Package Insert clearly and explicitly warns of the risk of serious infections and death. *See* Enbrel® Package Insert, pp. 11-20 (January 2001 #0311-07). The Package Insert thus informed the prescribing physician of the injuries alleged in this case. *See Parkinson*, 315 F. Supp. 2d at 749 (concluding as a matter of law that the warning issued to the physician was not inadequate as it warned of potential "guide wire tip separation," the precise injury alleged by the plaintiff).

Further, even assuming arguendo that Enbrel®'s warnings are found to be inadequate, Plaintiff's claims must still be dismissed because Plaintiff has not alleged sufficient facts to show causation. Under Pennsylvania law, even if "plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Demmler v. Smithkline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996) (quoting *Mazur v. Merck & Co.*, 742 F. Supp. 239, 262 (E.D. Pa. 1990)) (affirming summary judgment because the plaintiff could not demonstrate that a different warning would have caused the physician to not prescribe the pharmaceutical at issue).[11] Plaintiff has made no allegation that Decedent's physician would not have prescribed Enbrel® had an additional warning been given, and thus the negligence claim should be dismissed.

In sum, all of Plaintiff's claims that are based on Defendants' failure to warn should be dismissed either because Enbrel®'s warnings are adequate as a matter of law or because Plaintiff has not sufficiently alleged causation.

[11] In the event that the warnings are found to be inadequate, proximate cause is not presumed. *Demmler*, 671 A.2d at 1155.

II. PLAINTIFF'S CLAIM FOR GROSS NEGLIGENCE/PUNITIVE DAMAGES FAILS BECAUSE PLAINTIFF HAS NOT ALLEGED FACTS TO SUPPORT SUCH A CLAIM

Plaintiff's claim for gross negligence/punitive damages should be dismissed as well because under Pennsylvania law, there is no separate cause of action for gross negligence or punitive damages. *See Kline*, 2008 WL 4787577, at *3 (dismissing the plaintiff's claim for gross negligence because "Pennsylvania courts do not recognize degrees of negligence."); *Nix v. Temple Univ. of the Commonwealth Sys. of Higher Educ.*, 596 A.2d 1132, 1138 (Pa. Super. Ct. 1991) (affirming dismissal of the appellant's claim for punitive damages because "[a] request for punitive damages does not constitute a cause of action in an of itself.").

Alternatively, Plaintiff has not – and in some cases, *cannot* – plead the requisite intent for such damages under each theory of liability on which the claim for punitive damages is based. First, punitive damages are not recoverable in actions for breach of warranty. *See Johnson v. Hyundai Motor Am.*, 698 A.2d 631, 639 (Pa. Super. Ct. 1997) (stating that punitive damages are not recoverable in actions solely based upon breach of contract); *see also* 13 Pa. Cons. Stat. § 2714. As a result, to the extent the claim for punitive damages is based on Defendants' alleged breach of express or implied warranty, the claim must fail.

To the extent the claim for punitive damages is based on Defendants' other conduct, Plaintiff has failed to allege how Defendants' conduct was "so outrageous as to demonstrate willful, wanton or reckless conduct." *Hutchinson ex rel. Hutchinson v. Luddy*, 870 A.2d 766, 771 (Pa. 2005); *see also Richetta v. Stanley Fastening Sys., L.P.*, 661 F. Supp. 2d 500, 513 (E.D. Pa. 2009). Under Pennsylvania law, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in

conscious disregard of that risk." *Hutchinson*, 870 A.2d at 772; *see also Richetta*, 661 F. Supp. 2d at 513.

Plaintiff has not alleged any facts with particularity to meet the standard set forth in *Iqbal* and *Twombly*. While Plaintiff vaguely alleges that "Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others," (Cmplt., Lines 456-458), merely listing the elements of a cause of action is insufficient to satisfy the pleading standard. Further, it has already been demonstrated that Enbrel®'s Package Insert expressly and specifically warns of the risk of serious infections. *See* Enbrel® Package Insert, pp. 11-20 (January 2001 #0311-07).

Given the clear warning for infections – the precise injury allegedly suffered by Decedent – punitive damages are plainly not warranted. Indeed, other courts with similar punitive damages standards have rejected claims for punitive damages where a manufacturer's warning specifically described the main harm suffered by the plaintiff. In applying Alabama law in a products liability action, the Eleventh Circuit stated that it has "repeatedly held that the issue of punitive damages should not go to the jury when a manufacturer takes steps to warn the plaintiff of the potential danger that injured him; such acts bar a finding of wantonness." *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1317 (11th Cir. 2000) (internal quotations and citation omitted) (explaining wantonness as a conscious disregard of the safety of others). The same is true here. Because Defendants warned of the risk of infections, it cannot be said that they acted, or failed to

act, in conscious disregard of that risk. Plaintiffs claim for punitive damages should therefore be dismissed with prejudice.[12]

CONCLUSION

Plaintiff's 1st Amended Complaint should be dismissed in its entirety because the strict liability and breach of warranty claims are not cognizable when asserted against a manufacturer of prescription drugs, and the remaining negligence claim consists almost entirely of a formulaic recitation of the legal elements of the claim. Further, even if the negligence claim contains well-pleaded factual allegations, it *cannot* satisfy the standard even if pleaded with particularity because of the learned intermediary doctrine and lack of allegations regarding causation. Indeed, the Package Insert warned Decedent's prescribing physician of the risk of serious and fatal infections, the precise injury alleged here. Lastly, Plaintiff's claim regarding punitive damages must fail because Plaintiff did not plead the requisite intent necessary to sustain such a claim. The 1st Amended Complaint as a whole against Defendants should therefore be dismissed.

Respectfully submitted,

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[12] Plaintiff's Seventh Claim (for survival) and Eight Claim (for wrongful death) should be dismissed as well because those are also based on the underlying claims for strict liability, negligence, and breach of warranty and are merely a measure of damages.

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2011, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system that provided notification to the following:

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